

TABLE—EUP MICROBIAL PESTICIDES
TOXICOLOGY DATA REQUIREMENTS—Continued

| Guideline Number | Data Requirement | All Use Patterns | Test Substance | Test Notes |
|------------------|---------------------------|------------------|----------------|------------|
| 870.2400 | Acute eye irritation | R | MP, EP | 5 |
| 870.2500 | Primary dermal irritation | CR | MP, EP | 5 |

(d) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit microbial pesticides toxicology as referenced in the last column of the table contained in paragraph (c) of this section:

1. The acute oral toxicity/pathogenicity study is required to support the TGAI. However, it can be combined with the unit dose portion of the acute oral toxicity study, with an EP or MP test material to fulfill the requirement for the TGAI and the MP or EP in a single study, if the new protocol is designed to address the endpoints of concern.

2. Data not required for products whose active ingredient is a virus. For test materials whose size or consistency may prevent use of an intravenous injection, the intraperitoneal injection procedure may be employed.

3. Hypersensitivity incidents, including immediate type and delayed type reactions of humans or domestic animals occur during the testing or production of the TGAI, MP, or EP, or are otherwise known to the applicant must be reported if they occur.

4. Data must be submitted only for products whose active ingredient is a virus.

5. The 870 series studies for the MP and EP are intended to provide data on the acute toxicity of the product. Waivers for any or all of these studies may be granted when the applicant can demonstrate that the combination of inert ingredients is not likely to pose any significant human health risks. Where appropriate, the limit dose approach to testing is recommended.

6. Required when the product consists of, or under conditions of use that would result in an inhalable material (e.g., gas, volatile substances, or aerosol particulate).

§ 158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Terrestrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

| Guideline Number | Data Requirement | Use Patterns | | | | | | | | Test Substance | Test Notes |
|------------------|---------------------|--------------|---|---------------------------|---------------|-----------------------|------------------|------------------|-----------------|----------------|------------|
| | | Aquatic | | Terrestrial | | | | | | | |
| | | | | Food/ Feed/ Nonfood | Fore- stry | Resi- den- tial | Green- house | Indoor | Indus- trial | | |
| | | | | | | Out- door | Food/ Nonfood | Food/ Nonfood | | | |
| 885.4050 | Avian oral toxicity | NR | R | R | R | R | NR | NR | NR | TGAI | 1, 2 |

TABLE—EUP MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA
REQUIREMENTS—Continued

| Guideline Number | Data Requirement | Use Patterns | | | | | | | | Test Sub-stance | Test Notes |
|------------------|--|--------------|----|---------------------|------------|----------------|---------------|---------------|--------------|-----------------|------------|
| | | Aquatic | | Terrestrial | | | | | | | |
| | | | | Food/ Feed/ Nonfood | For-est-ry | Res-i-den-tial | Green-house | Indoor | In-dus-trial | | |
| | | | | | | Out-door | Food/ Nonfood | Food/ Nonfood | | | |
| 885.4200 | Freshwater fish toxicity/pathogenicity | NR | R | R | R | NR | NR | NR | NR | TGAI | 1, 2, 3 |
| 885.4240 | Freshwater invertebrate toxicity/pathogenicity | NR | R | R | R | NR | NR | NR | NR | TGAI | 1, 2, 3 |
| 885.4300 | Nontarget plant testing | NR | NR | NR | R | NR | NR | NR | NR | TEP | 1, 4 |
| 885.4340 | Nontarget insect testing | R | R | R | R | NR | NR | NR | NR | TGAI | 1, 5 |
| 885.4380 | Honey bee testing | R | R | R | R | NR | NR | NR | NR | TGAI | 1 |

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.

3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

Subpart W—Antimicrobial Pesticides [Reserved]

§ 158.2200 [Reserved]

Subparts X–Z [Reserved]

§§ 158.2300–158.2500 [Reserved]

PART 159—STATEMENTS OF POLICIES AND INTERPRETATIONS

Subparts A–C [Reserved]

Subpart D—Reporting Requirements for Risk/Benefit Information

Sec.

159.152 What the law requires of registrants.

159.153 Definitions.

159.155 When information must be submitted.

159.156 How information must be submitted.

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159.159 Information obtained before promulgation of the rule.

159.160 Obligations of former registrants.

159.165 Toxicological and ecological studies.

159.167 Discontinued studies.

159.170 Human epidemiological and exposure studies.

159.178 Information on pesticides in or on food, feed, or water.

159.179 Metabolites, degradates, contaminants, and impurities.